

## **II. REMARKS**

### **A. Introduction**

Applicants submit this Response in a bona fide attempt to (i) advance the prosecution of this case, (ii) answer each and every ground of objection and rejection as set forth by the Examiner, (iii) place the claims in a condition for allowance, and (iv) place the case in better condition for consideration on appeal. Applicants respectfully request reexamination and reconsideration of the above referenced patent application in view of this Response.

As indicated above, Claims 1-15 and 17-22 have been amended. Claim 16 is withdrawn and new Claims 23 and 24 have been added.

Applicants respectfully submit that the noted amendments merely make explicit that which was (and is) disclosed or implicit in the original disclosure. The amendments thus add nothing that would not be reasonably apparent to a person of ordinary skill in the art to which the invention pertains.

### **B. Response to Rejections**

#### **1. 35 U.S.C. § 112**

The Examiner has rejected Claims 3 and 4 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner contends that the specification and drawings are unclear regarding the “interengaging latch members.” Applicants have amended the claims throughout to clarify that the referenced “interengaging members” are “locking members” that engage with each other and are part of a “locking mechanism” that holds the piston in place when cocked. For example, paragraphs [0025] through [0027] describe Figs. 1 and 2 with reference to catch 26 and latch 30. As discussed, piston 14 is held in a cocked position when catch 26 and latch 30 are “releasably engaged.” The above amendments have replaced the term “latching” which generally connotes the same meaning, but Applicants believe the use of the term “locking” is more consistent with the body of the specification. Further, Applicants have replaced the term “interengaging” with “releasably engaging” to more closely track the specification. Finally, with respect to Claim 4, Applicants have replaced the term “stop” with the term “catch” as used in the specification. In light of these remarks and amendments, Applicants request that the Examiner withdraw the rejection of Claims 3 and 4 under 35 U.S.C. § 112, first paragraph.

## 2. 35 U.S.C. § 102

The Examiner has rejected Claims 1-2, 5-15 and 17-22 under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,827,297 to Boudjema. The Examiner contends that Boudjema discloses all of the limitations recited in the claims, including a body, a piston, an impact spring, a latching mechanism, a releasing mechanism and a penetrating member. With respect to Claims 7-10, 14-15 and 17, the Examiner further contends that Boudjema discloses a cap, a hold down spring and an indicator. Finally, the Examiner concludes that Boudjema clearly teaches the method steps of the claims.

Applicants respectfully request that the Examiner consider the following remarks. Boudjema is directed to a device suited to a substantially different purpose. While Applicants have disclosed a device and method for mechanically applying a microprotrusion member that is generally configured as a patch, Boudjema is directed to a tool that automatically drives a single needle relatively deeply into the scalp for the purpose of implanting at least several hair roots.

It is well established that a prior art reference anticipates an invention only when it specifically discloses each and every limitation of the claims. To clarify the differences between Applicants' invention and Boudjema, the claims have been amended to clarify that the piston must be configured to engage a substantially thin and flat member. Paragraph 5 of the specification describes that transdermal delivery devices generally have this shape. As discussed in the specification, Applicants' penetrating member comprises a patch having an array of microprotrusions/microblades adapted to pierce the stratum corneum to a relatively shallow depth, allowing the transdermal delivery or sampling of compounds. As such, the piston must engage the entire surface of the patch to cause uniform penetration.

In contrast, Boudjema's device drives only a single needle. As shown in Fig. 2, for example, piston 18 is not configured to engage a thin and flat member, but rather a long, narrow, single needle 20. As discussed in Boudjema at col. 4, lines 11 – 21, the engaging members of piston 18 are two rods 30 and 31 that clearly are not configured to engage a thin and flat member. The Examiner references a "microprotrusion array" as being disclosed by Boudjema, citing element number 33. However, this element is simply the end of needle 20, and thus, does not constitute an array of microprotrusions or microblades.

Therefore, Applicants respectfully submit that Boudjema does not disclose a piston configured to engage a thin and flat member, and therefore submits that this reference fails to

disclose all the claim limitations. Accordingly, Applicants request that the Examiner withdraw the rejection of Claims 1-2, 5-15 and 17-22 under § 102(b) as being anticipated by Boudjema.

With respect to the newly added claims, Claim 23 positively recites a retainer adapted to receive a thin and flat member and Claim 24 positively recites that the claimed device includes a penetrating member comprising a microprotrusion array. Accordingly, Applicants respectfully submit that the Boudjema reference does not disclose either of these claim limitations and that these new claims define patentable subject matter.

### III. CONCLUSION

Applicants having answered each and every ground of rejection as set forth by the Examiner, and having added no new matter, believe that this response clearly overcomes the references of record, and now submit that all claims in the above-referenced patent application are in condition for allowance and the same is respectfully solicited.

If the Examiner has any further questions or comments, Applicants invite the Examiner to contact their Attorneys of record at the telephone number below to expedite prosecution of the application.

Respectfully submitted,  
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